REMARKS

I. OVERVIEW/INTERVIEW SUMMARY

The Applicants and their attorney would like to thank Examiners Ali and Mitchell for the courtesies that they extended to the Applicants, Dennis Irlbeck and John Moenning, Applicant's attorney, and Mr. Kevin Burrow, an officer of the assignee, King Systems Corporation, at the interview that was held on 07 September 2006.

At the interview, the Applicants explained the workings of the invention to the Examiners, explained the manner in which the device functioned, the problems it overcame, and the ability of the present invention to solve the problems that the invention sought to solve.

Additionally, the applicants discussed the prior art cited by the Examiner in the 02 June 2005 Official Action, and pointed out the differences between the Applicant's invention and the art cited by the Examiner. In particular, it was pointed out to the Examiner that none of the Blasdell, Schauweker, Kwok, Banuch or Muto references disclosed or suggested the Applicants' claimed invention, as none disclosed or suggested the use of an inspiratory gas line for delivering inspiratory gases, wherein the inspiratory gas line had a patient end that was configured for insertion into the naris of a patient.

The arguments relating to the patentably distinguishable features of the applicants made invention essentially comprised an amplification of the remarks made in the pre-interview briefing memo that was forwarded to the Examiners prior to the interview.

At the interview, Examiners Mitchell and Ali reported that after reviewing the pre-interview briefing memo, they had conducted a "quick" search to determine whether any prior art existed that was believed by them to disclose or suggest the use of a device that placed

inspiratory gas directly within the naris of a patient, and as a result of this search, had discovered Brekke, et al. U.S. Patent No. 4, 151, 843 and Fischer U.S. Patent No. 4, 248, 218.

Examiners Ali and Mitchell reported that it was their intention to conduct a further search directed toward to this feature, after the receipt of a response to the 2 June 2005 Official Action from the applicants, as time did not permit them to conduct a full search prior to the interview. The Applicants promised to review the Fischer and Brekke references, and to consider such references when preparing their response to the 2 June 2005 Official Action.

The Examiners also stated that if allowance of the Claims was not achieved after this response, that a non-final rejection would be given to the applicants, based on the fact that any further rejection would, by necessity, be based on art not cited in a previous official action.

With this Response, the Applicants have attempted to address the Examiners' concerns and issues raised in the 2 June 2005 response, and also to address the two new references (Fischer and Brekke) given to the Applicants at the interview.

II. OBJECTIONS TO THE DRAWINGS

In the Official Action, the Examiner objected to the drawings, because the Examiner did not believe that an inflation valve was shown in the drawings. The Examiner's attention is directed to Figs. 2 and 4, wherein an air inflation valve 37 is shown.

The Examiner also stated that she was unclear about the nature of the item designated as "110" in Fig 1B. With this amendment, the Applicants have amended the specification to clarify that item 110 refers, in all instances to *dental anesthesia mask having an integrated eye protector device 110*, which is the composite device shown if Fig. 1B

The Applicants believe that the amendment and explanations given above address the Examiner's issues relating to the drawings, and thereby render the objections moot. Should the Examiner have any additional objections to the drawings, she is respectfully requested to contact the applicant's attorney, so that the applicants can take whatever steps are necessary to replace the drawings in condition for acceptance by the office.

III. STATUS OF CLAIMS/ELECTIONS/RESTRICTIONS

In the Official Action, the Examiner reiterated the Applicants' election of the dual gas line approved to, sub-species 2a. Accordingly, the Applicant has withdrawn Claims 13-18, 20, 22-23, 28-29, and 31-33 from consideration.

Of these claims, the only independent claim is Claim 31, that the Applicants by this amendment has cancelled. The remaining withdrawn claims all depend from independent claims that fit within the elected group. As such, the Applicants believes that if allowance of the independent claims of this application is achieved, that the withdrawn claims should be reinstated and allowed.

IV. REJECTIONS UNDER SECTION 112

In the Official Action, the Examiner objected to Claims 8, 12 and 14 under Section 112. With this Response, Claim 8 has been cancelled, thereby rendering moot the Examiner's objection.

The Examiner objected to Claim 12 as being indefinite, since it recites the presence of "an inspiratory port" which is also recited in Claim 9. The Applicants believe that the recitation

of "an inspiratory port" in Claim 12 is permissible, as Claim 12 depends from Claim 11, which, itself, depends from Claim 10. Claim 10 depends from Claim 1. As Claim 9 is not within the chain of claims which Claim 12 depends, the recitation of "an inspiratory port" in Claim 9 does not render the recitation of an inspiratory port in Claim 12 indefinite, as the recitation in Claim 12 of an inspiratory port is the first claim, in the chain of claims from which Claim 12 depends, within an inspiratory port is recited.

The Examiner also rejected Claim 5, based on the belief that the limitation, "the strap," had an insufficient antecedent basis. To overcome this problem, the Applicants have amended Claim 14 to now recite the presence of "a strap" at line 2 of Claim 14, so that the recitation of "the strap" line 5 of Claim 14 now has an appropriate antecedent basis.

By virtue of the explanations and amendments discussed above, the Applicants believe that all of the Examiner's objections to the claims based on Section 112 have been addressed appropriately, thereby rendering the Examiner's objections under Section 112 moot.

V. THE SUBSTANTIVE REJECTIONS

A. Rejections Based upon the Art Cited by the Examiner in the 2 June 2005 Official Action.

As alluded to above, the Examiner rejected the original claims then in the application under Sections 102 and 103 in view of Blasdell, Schauweker, Kwok, Banuch, and Muto.

As explained at the interview, none of these references disclose or suggest the presence of an inspiratory gas line having a patient end that was configured to be received within the naris of a patient for delivering inspiratory gas to the naris of a patient. Each of independent Claims 1, 21, 24 and 30 recite this feature, and none of these claims could either be anticipated or rendered

obvious by any of the art cited by the Examiner. In this regard, it should also be noted that newly added Claim 38 quotes a similar recitation, and as such, can not be either anticipated or rendered obvious by the art cited previously by the Examiner.

B. The Newly Cited Art

In the interview, the Examiner presented the Applicants with two (2) references that were heretofore unknown to the Applicants. These references included Fischer, U.S. Patent No. 4,248, 218; and Brekke et al,, U.S. Patent No. 4,151,843.

At the interview, the Examiner stated that these two recently found references were being given to the Applicants because the Examiner believed that both references showed devices that included outlets that were inserted into the naris of a patient.

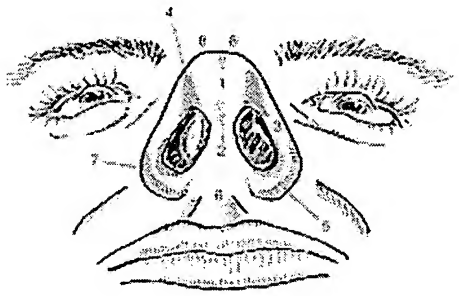
C. The Applicant's Claims Patentably Distinguish Their Invention from Fischer.

Fischer discloses an anesthesia gas mask having an inspiratory conduit 12, that enters into the side of the nose piece 14. The inspiratory conduit terminates at its intersection with the nose piece 14. Connector tube 30 attaches to the inspiratory conduit 12, and supports a rigid cannula 10. The cannula 10 includes a pair of nostril tubes 18, that presumably extend into the nostrils of the patient.

One difficulty with the device shown in the Fischer reference is the relatively rigid nature of the cannula, and the short length of the tube 18. Difficulties are likely to arise with this arrangement, due to the variation in nose size and shapes of different people.

A casual observation of different people will cause one to recognize that different people have noses of different sizes and shapes. Noses vary in length, width and other factors. Importantly, noses vary in the width of the columella, that separates the nose into two nostrils. (See item 2 of Figure A below) Because the columella width of patients differs widely, the Applicants have found that it is very helpful to be able to adjust the relative width and separation of the cannulas inserted into the nostrils to ensure that the nostril-engaging patient ends of the inspiratory port are properly positioned within the nostril.

Figure A: Base View of the nose



1 – infratip lobule
2 - columella
3 – alar sidewall
4 – facet, or soft-tissue triangle
5 - nostril sill
6 - columella-labial angle or junction
7 - alar-facial groove or junction
8 - tip defining points

This cannot be accomplished easily with the Fischer device. Because of the manner in which the Fischer device is made, it would appear difficult, if not impossible, for the practitioner

to adjust the positioning of the nostril tubes 18, once the nose piece is fitted over the nose. Additionally, the lateral separation of Fischer's nostril tubes appears to be fixed, thus making it difficult or impossible for the practitioner to adjust the lateral separation distance between the tubes to accommodate different columella widths.

The Applicants' device overcomes these difficulties by providing a patient end portion of the inspiratory tube that comprises a flexible cannula having a source end disposed on the outside air space, a middle portion extending through the dome portion and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient. Because a portion of the cannula is disposed outside the nose piece (dome), the practitioner can grasp the 'outside-of-the-mask' portion of the cannula to manipulate the cannula, to properly position the patient end of the cannula within the naris. Further, since the cannula is movable with respect to the face mask, the cannula position can be adjusted (both laterally and axially) even after the mask is positioned on the face of the user.

Significantly, this adjustment can be accomplished during a procedure without leaking gas into the environment, or without forcing the medical/dental practitioner to turn off the gas and thereby stop the sedation effect and/or interrupt the procedure.

Because of the relative length and flexibility of the Applicants' invention, the Applicants' cannula can be manipulated to be positioned over a wide variety of possible areas, to ensure that it is properly inserted in the patient's naris. For example, the length and flexibility of the cannula permits the user to vary the lateral separation of the two cannulas to accommodate noses having different sized (width) columellas.

This variability of positioning and the independence of movement of the cannula with respect to the nose piece is not found in the Fischer device. In Fischer, the position of the nostril tubes 18 is fixed relative to the connector tube 14. More importantly, the position of the cannula 10 is fixed in its position relative to the nose piece 14, through the engagement of the connector tube 30 with the inspiratory tube 12, and the cannula 10, and hence, the nose piece 14.

If the practitioner desired to adjust the Fischer device during a procedure, the practioner would be required to either; (1) lift the face mask off the patient during the delivery of gas, and thereby cause gas leakage into the procedure room environment; or (2) alternately, to prevent such leakage, turn off the gas and interrupt the procedure and the sedation of the patient before making the adjustment. By contrast, the Applicant's mask permits such adjustments to be made during the delivery of gas without either causing gas leakage into the environment, or requiring the practioner to interrupt the sedation and the procedure.

The Applicants' arrangement also permits the length of the cannula within the interior of the face mask to be varied. The Applicants' design enables the practitioner to insert a relatively long portion of the cannula interiorly of the face mask, to ensure that the cannula is inserted deeply enough within the naris of the patient to help ensure that gas flowing from the cannula is received within the body of the patient. Alternately, the practitioner can pull the cannula out, so that only a short length of the cannula is contained within the interior of the nose mask. A shorter length of cannula placed inside the mask may be appropriate if the patient has a large or long nose, that is placed close to the dome. In such a large-nosed patient, only a short length of cannula is necessary to have the cannula inserted at a proper depth within the naris. This "axial

variability" of the Applicants' invention is not possible with the configuration shown in the Fischer reference.

The Examiner's attention is now directed to dependent Claims 1, 21, and 30. It will be noted that each include a recitation relating to the feature described above. In particular, each of these claims recite that "the patient end portion [comprises] a flexible cannula having a source end disposed in the outside air space, a middle portion extending through the dome portion, and a patient end configured for received within the naris of the patient for delivering inspiratory gas to the naris of the patient. As described above, this feature is neither disclosed or suggested by Fischer.

The Examiner's attention is now directed to Claims 24 and 38. Each of Claims 24 and 38 include a recitation that face mask includes an elbow, and an exhaust line having a machine end and a patient end that is capable of being connecting to the elbow, and that the exhaust line is positioned by the elbow to extend over the forehead of the patient. The Examiner's attention is directed to Figs. 5b, 7b, 8 and 9 that show the relationship of the exhaust line 18 to the forehead of the patient.

Returning back to the Fischer reference, it will be noted that Fischer's inspiratory tube and expiratory tube extend outwardly from the side of the mask. In operation, a "side-loading" mask, such as that shown in Fischer, causes the inspiratory tubes and expiratory tubes to be directed along the cheeks of the user, and along side the side of the patient. Another example of a "side loading" mask was shown to the Examiner by Dr. Moenning during the interview.

Through years of using such devices, the Applicants have found that such devices are ergonomically disadvantageous to the practitioner operating on the patient. Because many procedures are rather lengthy, practitioners (especially dentists and oral surgeons) prefer to sit while performing a procedure on the patient. The side hanging hoses on masks, such as that shown in Fischer, force the oral surgeon to place herself in a position where she can work on the patient, while not interfering with the hoses. This causes the oral surgeon to position herself further away from the patient that she would prefer.

By contrast, the Applicants' exhaust line hangs over the forehead of the patient and over the patient's head, and then leads back to the anesthesia device. As such, no pipes or tubes are hanging over the patient's side. Through the Applicants' configuration, the oral surgeon does not need to "work around" the side-hanging tubes. As such, the oral surgeon can get closer to the patient, and assume a more ergonomically correct position when operating on the patient.

In summary, Fischer does not suggest or disclose an "over the forehead" arrangement as recited in Applicants' Claims 24 and 38.

C. The Brekke Reference

The Examiner's attention is now directed to Brekke.

Brekke discloses a face mask that comprises a double walled-hollow mask member 12. The mask member 12 includes a front wall 12 and an inner wall 20, that, at the bottom, form a pair of spaced protrusions 28 and 30 "formed with the openings 32 and 34 respectively," both of which communicate with the hollow interior 27. Nostril cuffs 28 and 30 are of a length "to

extend slightly into the nostrils of a patient receiving the anesthesia to form a sealing engagement therewith, and the front wall is of such a lateral extent that the side walls 24 and 26 lie adjacent to the side of the nose".[1]

From this description, it is clear that Brekke discloses a double-walled face mask that includes a fluid passageway formed by the space between the two walls. Brekke does not disclose or suggest the Applicants' inspiratory lines that extend from outside to inside of the face mask.

The Examiner's attention is next directed to Fig. 8 of Brekke. Fig. 8 includes a gas flow control device 38 to which is attached a cannula 76. The outer ends of the tubes 80 and 82 are formed with enlarged nose cuff ends 84 and 86 respectively.

It should be noted that it appears that the device shown in Fig. 8 of Brekke is a "mask-less" device, wherein the anesthesia device comprises primarily the gas control valve and the two nostril tubes. As Brekke states, "the device of Fig. 8 is used by the oral and maxillofacial surgeon when the patient is anesthetized in the surgical planes of anesthesia." This is contrasted with use of the double-wall hollow nasal mask 12 for maintenance of inhalation sedation or amnesic claims of anesthesia. As such, Fig. 8 can also not disclose just the Applicants' inspiratory line, as there exists in Fig. 8 no face mask through which the inspiratory lines penetrate.

Additionally, it should be noted that the devices shown in Brekke do not include an anesthesia exhaust line that extends over the forehead of the patient. Rather, the lines 57 that

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[1] See Brekke, U.S. Patent No. 4, 151, 843 at col. 2, ll 43-54.

provide exhaust are draped over the side of the patient's head in a "V-like" arrangement, thus inducing the same difficulties as discussed above in connection with the Fischer device.

VI AMENDMENTS TO THE CLAIMS

As discussed above, the independent claims have been amended to more particularly recite the differences discussed above between the Applicants' invention and the prior art. The Applicants submit that their amended claims patentably distinguish their invention from the art of record, as neither of the references disclose or suggest those features incorporate into the claims.

Turning now to "newly added" dependent claims 34-36 and 38, it should be noted that these claims further distinguish the Applicants' invention from the art of record, as none of the features disclosed in these dependent claims is believed to be either disclosed or suggested by any of the art of record.

VII SUMMARY

Applicants believe that the present application, as amended, is in condition for allowance. Re-examination and reconsideration, culminating in the allowance of all claims, in due course, is respectfully requested.

If the Examiner has any questions relating to this Amendment, or would like to discuss any issues about this case with the Applicants' Attorney, she is respectfully requested to contact

the Applicants' Attorney, E. Victor Indiano, at (317) 822-0033, or via e-mail at Vic@IPLawIndiana.com.

VIII. REQUEST FOR EXTENSION OF TIME

If necessary, Applicants request that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicants request that any required fees needed beyond any submitted with this Response, be charged to the account of **E. Victor Indiano, Deposit Account Number 50-1590**.

Respectfully submitted,

E. Victor Indiano
Reg. No. 30,143

cc: Kevin Burrow
Dennis Irlbeck
John Moenning
Thomas McGrail

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